**General Information**

CAS Number: 102-71-6
Common Name: Triethanolamine

## II. Physical-Chemical Data

### A. Melting Point

This endpoint is not applicable. Polyphosphoric acid esters with triethanolamine, sodium salts is supplied as an aqueous solution.

## B. Boiling Point

This endpoint is not applicable. Polyphosphoric acid esters with triethanolamine, sodium salts is supplied as an aqueous solution.

## C. Vapor Pressure

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Measured |
| GLP: | No |
| Remarks: | None |

**Results**

| | |
|---|---|
| Vapor PressureValue: | 0.000477 Pa at 25$^{o}$C |
| Remarks: | None |

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions; endpoint was provided in a reliable reference text. |

**Reference** Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

## D. Partition Coefficient

No data exists for this endpoint for polyphosphoric acid esters with triethanolamine, sodium salts. Arch proposes to conduct a study according to OECD (TG 107) guidelines and GLP standards to obtain a value for this endpoint.

## E. Water Solubility

No data exists for this endpoint for polyphosphoric acid esters with triethanolamine, sodium salts. Arch proposes to conduct a study according to OECD (TG 105) guidelines and GLP standards to obtain a value for this endpoint.

## III. Environmental Fate Endpoints

### A. Photodegradation – Entry 1 of 2

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Other (calculated) |
| GLP: | Not stated |
| Remarks: | None |

**Results**

| | |
|---|---|
| Hydroxyl radicals reaction: | |
| OH Rate Constant: | 1.04 E-12 $cm^3$/molecule-sec |
| Degradation: | 50% after 4 hours |
| Ozone reaction: | No ozone reaction estimation |
| Remarks: | None |

**Data Quality:**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions. Endpoint was provided in a reliable reference text. |

**Reference**

Atkinson, R. Inter. J. Chem. Knot 19: 799-828. 1987. Listed in: Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

**Other**

Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

**Entry 2 of 2 for Photodegradation**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Estimation |
| Model: | Atmospheric oxidation |
| Remarks: | None |

**Results**

| | |
|---|---|
| Hydroxyl radicals reaction: | |
| OH Rate Constant: | 110 E-12 $cm^3$/molecule-sec |
| Half-Life: | 1.16 hours |
| Ozone reaction: | No ozone reaction estimation |
| Remarks: | None |

**Data Quality:**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | Reliable with restrictions. Endpoint was provided by computer modeling. |

**Reference:** AopWin v.1.90. (EPI Suite™ v.3.10). Downloadable at http://www.epa.gov/oppt/exposure/docs/episuitedl.htm. ©2000 U. S. Environmental Protection Agency.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

**B. Stability in Water**

No data exists for this endpoint for polyphosphoric acid esters with triethanolamine, sodium salts. Arch proposes to conduct a study according to OECD (TG 111) guidelines and GLP standards to obtain a value for this chemical. Confirmation of the hydrolysis of polyphosphoric acid esters with triethanolamine, sodium salts will allow bridging of this chemical to triethanolamine for this endpoint.

## C. Biodegradation – Entry 1 of 2

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | OECD Guideline 302B "Inherent biodegradability: Modified Zahn-Wellens Test" |
| Test type: | Aerobic |
| GLP: | Not stated |
| Year: | 1979 |
| Contact time: | 8 days |
| Inoculum: | Activated sludge |
| Concentration: | 400 mg/l |
| Remarks: | None |

**Results**

| | |
|---|---|
| Degradation: | 82% after 8 days |
| Results: | Inherently biodegradable |
| Remarks: | None |

**Conclusions** The biodegradability of the test substance has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 1A |
| Remarks: | Reliable without restrictions; OECD guideline study. |

**Reference** Gerike, P., Fischer, W. K. 1979. A Correlation Study of Biodegradability Determinations with Various Chemicals in Various Tests. ECETOX. Environ. Safety. 3: 159-173.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

**Entry 2 of 2 for Biodegradation**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | OECD Guideline 302 B |
| Test type: | Aerobic |
| GLP: | Not stated |
| Year: | 1980 |
| Contact time: | 14 days |
| Concentration: | 1000 mg/l |
| Inoculum: | Domestic sewage |
| Remarks: | None |

**Results**

| | |
|---|---|
| Degradation: | 89 % after 14 days |
| Results: | Inherently biodegradable |
| Kinetic: | Not stated |
| Breakdown products: | Not stated |
| Remarks: | None |

**Conclusions** The biodegradability of the test substance has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 1A |
| Remarks: | Reliable without restrictions; OECD guideline study. |

**Reference** Zahn, R. and Wellens, H. 1980. Examination of Biological Degradability through the Batch method – further Experience and New Possibilities of Usage. Z. Wasser Abwasser Forsch. 13: 1-7.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

## D. Transport between Environmental Compartments (Fugacity)

**Test Substance**

Identity: Triethanolamine
Remarks: None

**Method**

Method: Calculation according to Mackay, Level I
Remarks: Data used:
Molecular mass: 149.2
Log10 octanol/water partition coefficient: -1.59
Water solubility: 10,000 mg/l (As triethanolamine is fully miscible with water, an estimated value as shown was used.)
Vapor pressure: 0.000477 Pa at 25°C
Amount of chemical dispersed: 10 moles

**Results**

Distribution to each medium

| | Percent Distribution |
|---|---|
| Air | <0.001 |
| Water | 99.999 |
| Soil | <0.001 |
| Sediment | <0.001 |

Remarks: None

**Reference**

Comber, M. I. H. Zeneca Brixham Environmental Laboratory. Letter to M. G. Penman. ICI Chemicals & Polymers Limited. 1993.

**Other**

Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

## IV. Ecotoxicity

### A. Acute Toxicity to Fish – Entry 1 of 2

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Static |
| Test type: | 24-hour $LC_{50}$ |
| Analytical monitoring: | No data |
| Organism: | *Carassius auratus* (goldfish, freshwater species) |
| Year: | 1979 |
| GLP: | No data |
| Statistical methods: | None |
| Remarks: | The test procedure was in accordance with American Public Health Association guideline. Goldfish of uniform length (average 6.2±0.7 cm) and weight (average 3.3 g) and in good health were used for the assay. Triethanolamine was tested at a series of concentrations. In each test 10 fish were exposed in 25 liters of solution (pH – 9.9; temperature – 20°C) contained in all glass tanks. The solutions were aerated throughout the test period. |

**Results**

| | |
|---|---|
| $LC_{50}$ (24 hours): | > 5000 mg/l |
| Remarks: | None |

**Conclusion** The acute toxicity of the test substance has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 2A |
| Remarks: | Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles. |

**Reference** Birdie, A. L., C. J. M. Wolff and M. Winter. 1979. The Acute Toxicity of Some Petrochemicals to Goldfish. Water Res. 13: 623-626.

| | |
|---|---|
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |

**Entry 2 of 2 – Acute Toxicity to Fish**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | 97 % |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Not stated |
| Test type: | Acute |
| GLP: | No data |
| Year: | 1987 |
| Species: | *Pimephales promelas* |
| Analytical monitoring: | Yes |
| Exposure period: | 96 hours |
| Statistical methods: | None |
| Remarks: | The conditions of the test solutions were as follows: pH – 7.8; temperature – 25.7°C; dissolved oxygen – 7.3 mg/l. |

**Results**

| | |
|---|---|
| $LC_{50}$ (96 hours): | 11,800 mg/l |
| Remarks: | The affected fish lost schooling behavior, were hyperactive and darkly colored, had increased respiration and lost equilibrium prior to death. |

**Conclusion** The acute toxicity of the test substance has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 2A |
| Remarks: | Reliable with restriction; Acceptable, well-documented publication report which meets basic scientific principles. |

**Reference** Geiger, D. L., L. T. Brooks and D. J. Call. Acute Toxicities for Organic chemicals to Fathead Minnows (*Pimephales promelas*). Volume V. Center for lake Superior Environmental Studies, University of Wisconsin – Superior. 1984-88.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

## B. Acute Toxicity to Daphnids – Entry 1 of 2

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | DIN 38412 part 11 |
| Test type: | Acute static |
| GLP: | No data |
| Year: | 1982 |
| Species: | *Daphnia magna* |
| Analytical monitoring: | No |
| Exposure period: | 24 hours |
| Statistical methods: | No statistics applied to data |
| Remarks: | Test medium was not neutralized. Concentrations were nominal. |

**Results**

| | |
|---|---|
| $EC_{50}$ (24 hours): | 1386 mg/l |
| $EC_{100}$ (24 hours): | 2455 mg/l |

**Conclusions** The 24-hour acute toxicity of the test substance to *Daphnia magna* has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 2A |
| Remarks: | Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles. |

**Reference** Bringmann, G. and R. Kuhn. 1982. Z. Wasser Abwasser Forsch. 15: 6-11.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

**Acute Toxicity to Daphnids – Entry 2 of 2**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Not stated |
| Test type: | Acute static |
| GLP: | No data |
| Year: | 1987 |
| Species: | *Daphnia magna* |
| Analytical monitoring: | No |
| Exposure period: | 24 hours |
| Statistical methods: | No statistics applied to data |
| Remarks: | Test was conducted at pH 7.6-7.7 and 20-22$^{o}$C. |

**Results**

| | |
|---|---|
| $EC_{50}$ (24 hours): | 1390 mg/l |

**Conclusions** The 24-hour acute toxicity of the test substance to *Daphnia magna* has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 2A |
| Remarks: | Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles. |

**Reference** Bringmann, G. and R. Kuehn. 1987. Results of the damaging effect of water pollutants on *Daphnia magna*. Z. Wasser Abwasser Forsch. 20: 161-166.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

## C. Acute Toxicity to Aquatic Plants (Algae) – Entry 1 of 2

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | DIN 38412, Part 9 |
| Test type: | Acute static growth inhibition |
| GLP: | Not stated |
| Year: | 1986 |
| Species: | *Scenedesmus subspicatus* |
| Analytical monitoring: | No |
| Exposure period: | 96 hours |
| Statistical methods: | No statistics applied to data |
| Remarks: | The assay was conducted with and without neutralized triethanolamine. Concentrations were nominal. |

**Results**

| | Neutralized | Non-neutralized |
|---|---|---|
| $EC_{10}$: | 13.2 mg/l | 7.1 mg/l |
| $EC_{50}$: | 910 mg/l | 169 mg/l |
| $EC_{90}$: | 62,500 mg/l | 4030 mg/l |

**Conclusions** The 96-hour acute toxicity of the test substance to *Scenedesmus subspicatus* has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 2A |
| Remarks: | Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles. |

**Reference** Amann, W. and A. Stainhauser. 1986. Umweltforschungsplan des BMI, UFOPLAN Nr. 102 05 308. im Auftrag des Umweltbundesamtes.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

**Acute Toxicity to Aquatic Plants (Algae) – Entry 2 of 2**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | DIN 38412, Part 9 |
| Test type: | Acute static growth inhibition |
| GLP: | Not stated |
| Year: | 1990 |
| Species: | *Scenedesmus subspicatus* |
| Analytical monitoring: | No |
| Exposure period: | 72 hours |
| Statistical methods: | No statistics applied to data |
| Remarks: | None |

**Results**

| | |
|---|---|
| $EC_{10}$: | 110 mg/l |
| $EC_{50}$: | 750 mg/l |

**Conclusions** The 72-hour acute toxicity of the test substance to *Scenedesmus subspicatus* has been adequately characterized.

**Data Quality**

| | |
|---|---|
| Reliability: | 2A |
| Remarks: | Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles. |

**Reference** Kuhn, R. and M. Pattard. 1990. Results of the Harmful Effects of Water Pollutants to Green Algae (*Scenedesmus subspicatus)* in the Cell Multiplication Inhibition Test. Water. Res. 24: 31-38.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

## V. Mammalian Toxicity

### A. Acute Toxicity – Entry 1 of 5

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | 91.8 % triethanolamine; 6.1 % diethanolamine |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Oral toxicity |
| GLP: | No data |
| Year: | 1973 |
| Species/Strain: | Rat/strain not stated |
| Sex: | Male/Female |
| Number of animals/ sex/dose: | 5 |
| Vehicle: | Not stated |
| Route of administration: | Oral (gavage) |
| Remarks: | Five dose groups of 10 rats each were administered the test substance between 3.64 and 10.0 g/kg. Animals were observed for mortality and clinical signs for 14 days. |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ is 7.39 g/kg |
| Mortality rate: | Not stated |
| Remarks: | There was slight to moderate degrees of hemorrhagic rhinitis in rats administered doses equal to or greater than 7.14 g/kg. |

**Conclusions**

| | |
|---|---|
| Remarks: | The acute oral $LD_{50}$ is 7.39 g/kg. |

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study. |

| | |
|---|---|
| **Reference** | Cosmetic Ingredient Review. 1983. Final Report on the Safety Assessment of Triethanolamine, Diethanolamine and Monoethanolamine. J. Am. Coll. Toxicol. 2 (7): 173-235. |
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |

**Acute Toxicity – Entry 2 of 5**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Purity not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Oral toxicity |
| GLP: | No data |
| Year: | 1951 |
| Species/Strain: | Rat/strain not stated |
| Sex: | Males |
| Number of animals/ sex/dose: | 6 animals/dose |
| Vehicle: | Water |
| Route of administration: | Oral (gavage) |
| Remarks: | None |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ is 9.11 g/kg |
| Mortality rate: | Not stated |
| Remarks: | No clinical information given. |

**Conclusions**

| | |
|---|---|
| Remarks: | The acute oral $LD_{50}$ is 9.11 g/kg. |

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study. |

**Reference**

Smyth, H. F., Carpenter, C. P. and Weil, C. S. 1951. Range-finding toxicity data: List IV. Arc. Ind. Hyg. Occ. Med. 4: 119-22.

**Other**

Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

**Acute Toxicity – Entry 3 of 5**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Commercial grade |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Oral toxicity |
| GLP: | No data |
| Year: | 1940 |
| Species/Strain: | Rat/strain not stated |
| Sex: | Not stated |
| Number of animals/ sex/dose: | 10 animals/dose |
| Vehicle: | Test article was administered undiluted. |
| Route of administration: | Oral (gavage) |
| Dose range: | 1 to 12 g/kg |
| Remarks: | None |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ is 8 g/kg |
| Mortality rate: | Not stated |
| Remarks: | The average survival time after administration was 24 hours. The author states that mortality was probably the result of the alkalinity of the material. The gross pathological change was confined to the gastrointestinal tract. The stomach was distended, congested and showed hemorrhagic areas. The blood vessels of the large and small intestines were distended. Liver, kidney, spleen and lungs showed no gross pathological changes. Before death, most of the animals had an intense diarrhea and were completely prostrate. |

**Conclusions**

| | |
|---|---|
| Remarks: | The acute oral $LD_{50}$ is 8 g/kg. |

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study. |

| | |
|---|---|
| **Reference** | Kindsvatter, V. H. 1940. Acute and chronic toxicity of triethanolamine. J. Indus. Hyg. Toxicol. 22 (6): 206-212. |
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |

**Acute Toxicity – Entry 4 of 5**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Purity not stated |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method/guideline followed: | Per method used for inhalation toxicity at BASF |
| Type: | Inhalation toxicity |
| GLP: | No |
| Year: | 1966 |
| Species/Strain: | Rat/strain not stated |
| Sex: | Not stated |
| Number of animals/ sex/dose: | Not stated |
| Vehicle: | None |
| Route of administration: | Inhalation |
| Remarks: | The animals were exposed to a saturated atmosphere of triethanolamine for 8 hours at $20^{o}$ C. |

**Results**

| | |
|---|---|
| Value: | $LC_{50}$ is greater than a saturated atmosphere. |
| Mortality rate: | No mortality. |
| Remarks: | No clinical information given. |

**Conclusions**

| | |
|---|---|
| Remarks: | The acute inhalation $LC_{50}$ is greater than a saturated atmosphere. |

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study. |

**Reference** BASF AG. 1966 Abteilung Toxikologie. Unpublished report. ZST-Nr. SV/307.

| | |
|---|---|
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |

**Acute Toxicity – Entry 5 of 5**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | 91.8 % triethanolamine; 6% diethanolamine |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Type: | Dermal toxicity |
| GLP: | No |
| Year: | 1973 |
| Species/Strain: | Rat/strain not stated |
| Sex: | Not stated |
| Number of animals/ sex/dose: | Not stated |
| Vehicle: | None |
| Route of administration: | Dermal |
| Remarks: | None |

**Results**

| | |
|---|---|
| Value: | $LD_{50}$ is greater than 2 g/kg |
| Mortality rate: | None |
| Remarks: | No clinical information given. |

**Conclusions**

| | |
|---|---|
| Remarks: | The acute dermal $LD_{50}$ is greater than 2 g/kg. |

**Data Quality**

| | |
|---|---|
| Reliability: | 2D |
| Remarks: | The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study. |

**Reference** Cosmetic Ingredient Review. 1983. Final Report on the Safety Assessment of Triethanolamine, Diethanolamine and Monoethanolamine. J. Am. Coll. Toxicol. 2 (7): 173-235.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

**B. Genetic Toxicity – Entry 1 of 3**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Reported as reagent grade |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Ames/*Salmonella* Bacterial Point Mutation Assay |
| Type: | Reverse mutation assay |
| Test system: | Bacteria |
| GLP: | Not stated |
| Year: | 1982 |
| Species/Strain: | *Salmonella typhimurium/* TA98 and TA100. |
| Metabolic activation: | Test conducted with and without metabolic activation. |
| Concentrations tested: | 0 to 20,000 µg/plate |
| Remarks: | Triethanolamine was dissolved in 0.1 ml of distilled water and added to 0.5 ml of S9 mix or 0.1 M sodium phosphate buffer (pH 7.4) with 0.1 ml of bacterial culture. The mixtures were incubated for 20 minutes at 37° C with shaking. It was then mixed rapidly with 2 ml of molten soft agar containing 0.1 µmole of L-histidine and biotin, poured onto minimal glucose agar plates and incubated for 2 days at 37° C. S9 mix was prepared form the post-mitochondrial supernatant of the liver of rats that had been pretreated with polychlorinated biphenyl for induction of microsomal enzymes. Concurrent solvent (water) and positive controls (without activation – 4-nitroquinoline 1-oxide; with activation – benzo[a]pyrene) were tested with and without the metabolic activation systems. |

**Results** There was no difference between controls and all concentrations tested in revertant colonies/plate with or without metabolic activation.

**Conclusions**

| | |
|---|---|
| Remarks: | The test substance did not induce mutations in this test system with and without metabolic activation. |

**Data Quality**

| | |
|---|---|
| Reliability: | 1B |

| | |
|---|---|
| Remarks: | Reliable without restriction; comparable to guideline study. |
| **Reference** | Inoue, K., T. Sunakawa, K. Okamoto and Y. Tanaka. 1982. Mutagenicity tests and in vitro transformation assays on triethanolamine. Mut. Res. 101: 305-313. |
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |

**Genetic Toxicity – Entry 2 of 3**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Reported as practical grade |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | Ames/*Salmonella* Bacterial Point Mutation Assay |
| Type: | Reverse mutation assay |
| Test system: | Bacteria |
| GLP: | Not stated |
| Year: | 1986 |
| Species/Strain: | *Salmonella typhimurium/* TA98, TA100, TA 1535 and TA 1537. |
| Metabolic activation: | Test conducted with and without metabolic activation. |
| Concentrations tested: | 0 to 3,333 µg/plate |
| Remarks: | Male Sprague-Dawley rats were used to prepare the S-9 fraction. Liver microsomal enzymes were induced with polychlorinated biphenyl (Arochlor 1254). The S-9 mix was prepared immediately prior to the assay and consisted of the following per ml: 0.04 M β-nicotinamide adenine dinucleotide phosphate, 0.10 ml; 0.05 M glucose-6-phosphate, 0.10 ml; 1.0 M $NaH_2PO_4$, pH 7.4), 0.10 ml; and distilled water, 0.56 ml. Triethanolamine was assayed in the preincubation assay. To each test tube maintained at 37° C was added in the following order: 0.5 ml of S-9 mix or 0.1 M $PO_4$ buffer (pH 7.4), 0.05 ml of the overnight culture, and 0.05 ml of solvent or chemical dilution. The mixture was mixed and allowed to incubate without shaking at 37° C for 20 minutes, at which time 2.0 ml of molten top agar supplemented with 0.5 mM L-histidine and 0.5 mM D-biotin were added. The contents of the tubes were mixed and pured onto 25 ml of minimal glucose bottom agar in 15 x 100-mm plastic petri dishes. When the top agar has solidified, the plates were nverted and incubated at 37° C for 48 hours. Concurrent solvent (water) and positive controls (without activation – sodium azide for TA 1535 and TA 100, 4-nitro-o-phenylenediamine for TA 98, 9-aminoacridine for TA 1537; with activation – 2-aminoanthracene for |

| | |
|---|---|
| | all strains) were tested with and without the metabolic activation systems. |
| **Results** | There was no difference between controls and all concentrations tested in revertant colonies/plate with or without metabolic activation. |
| **Conclusions** | |
| Remarks: | The test substance did not induce mutations in this test system with and without metabolic activation. |
| **Data Quality** | |
| Reliability: | 1B |
| Remarks: | Reliable without restriction; comparable to guideline study. |
| **Reference** | Mortelmans, K., S. Haworth, T. Lawlor, W. Speck, B. Tainer and E. Zeiger. 1986. *Salmonella* Mutagenicity Tests: II. Results from the Testing of 270 Chemicals. Environ. Mut. 8, Supplement 7: 1-119. |
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |

**Genetic Toxicity – Entry 3 of 3**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Reported as reagent grade |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method: | That of Ishidate and Odashima (1977) as reported in Mutation Research 48: 337-354. |
| Type: | Cytogenetic assay |
| Test system: | Chinese hamster lung cells |
| GLP: | Not stated |
| Year: | 1982 |
| Species/Strain: | CHL cells |
| Concentrations tested: | 0 to 100 µg/ml |
| Remarks: | Inocula of 2 x $10^4$ CHL cells suspended in Eagle's MEM supplemented with 10% fetal calf serum were seeded into 60-mm petri dishes. After cultivation for 3 days, a test chemical was then added and incubation was continued for 24 or 48 hours. Colcemid was added to the media at a final concentration of 0.2 µg/ml for the last 2 hours of incubation. After trypsinization, the cells were incubated in hypotonic solution (0.075-M KCl) for 15 minutes at 37° C. The cells were then fixed with ice-cold fixative (methanol:glacial acetic acid, 3:1) with 3 changes of the solution. A few drops of the cell suspension were placed on a slide on wet blotting paper, and the slide was stained with Giemsa. At each concentration of the chemical, 100 metaphase cells were examined for chromosomal aberrations. The controls consisted of a tissue culture control, vehicle control (DMSO) and a positive control (N-methyl-N'-nitro-N-nitrosoguanidine. |

**Results** There was no difference between controls and all concentrations tested in chromatid gaps, chromatid breaks, chromatid exchanges or number of polyploid cells.

**Conclusions**

| | |
|---|---|
| Remarks: | The test substance did not induce chromosome aberrations in this test system with and without metabolic activation. |

**Data Quality**

| | |
|---|---|
| Reliability: | 1B |
| Remarks: | Reliable without restriction; comparable to guideline study. |

**Reference**

Inoue, K., T. Sunakawa, K. Okamoto and Y. Tanaka. 1982. Mutagenicity tests and in vitro transformation assays on triethanolamine. Mut. Res. 101: 305-313.

**Other**

Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

## C. Repeated Dose Toxicity – Entry 1 of 2

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | 88.5 % triethanolamine and 6 % diethanolamine |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Test type: | Oral |
| Year: | 1976 |
| GLP: | No data |
| Species: | Rat |
| Strain: | Not stated |
| Number and sex: | 20 males and 20 females/group. Animals were exposed to 4 dose levels ranging from 0 to 1000 mg/kg. |
| Route of administration: | Oral (incorporation into the feed) |
| Duration of test: | 91 days |
| Control group and treatment: | No information on control group specified |
| Post-exposure observation period: | Not specified |
| Methods: | Animals were dosed for 91 days and then evaluated for hematologic effects and pathological change. |

**Results**

| | |
|---|---|
| NOAEL: | 1000 mg/kg |
| Remarks: | No gross or histopathological evidence of a treatment-related effect. No significant hematologic effects. |

**Conclusions**

| | |
|---|---|
| Remarks: | Triethanolamine is of low toxicity from repeated exposure up to 91 days with a NOAEL of at least 1000 mg/kg. |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 2B |
| Remarks: | Reliable with restrictions. Basis data provided. |

**Reference:** CTFA. 1976. Submission of data by CTFA (2-5-55). 91 Day subchronic oral toxicity using triethanolamine. Cited in CIR, 1983.

| | |
|---|---|
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |

**Repeated Dose Toxicity – Entry 2 of 2**

**Test Substance**

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | 99 % reagent grade |
| Remarks: | None |

**Method**

| | |
|---|---|
| Method/guideline followed: | Not stated |
| Test type: | Oral |
| Year: | 1986 |
| GLP: | No data |
| Species: | Rat |
| Strain: | Fischer 344 |
| Number and sex: | 50 animals/sex/group |
| Route of administration: | Oral (incorporation into the drinking water) |
| Duration of test: | 104 weeks |
| Dose level: | 1 or 2 % triethanolamine in the drinking water which, based on water consumption and body weight, resulted in a dose of 425 to 475 mg/kg in the low dose group and 900 to 925 mg/kg in the high dose group. |
| Control group and treatment: | Concurrent control group (50 rats/sex) administered the solvent (water). |
| Post-exposure observation period: | 9 weeks |
| Methods: | Animals were randomly divided into 3 groups, each consisting of 50 rats/sex. Rats were given the test article solutions ad libitum. At week 60 loss of body weight gain and mortality rate increased in the females in the 2 % group. Therefore, the concentration of triethanolamine was reduced by one-half for the females in this group. Triethanolamine solutions were freshly prepared once/week and the amount of solution consumed was measured to calculate the triethanolamine intake. All animals were observed daily and clinical signs and mortality were recorded. Body weights were measured once/week during the first 13 weeks of the study and then once every 4 weeks. At the end of the treatment and observation periods the following organs were evaluated for histopathological change: brain, spinal cord, |

peripheral nerves, pituitary, thyroid, thymus, lungs, heart, liver spleen, pancreas, adrenals, kidneys, urinary bladder, salivary glands, tongue, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, gonads, accessory genital organs, mammary glands, lymph nodes, skin, musculature, sternum, femur, eyes, and nasal cavity.

**Results**

NOAEL: 1000 mg/kg

Remarks: None of the treatment groups showed a significant increase in the incidence of any specific tumors over the corresponding control group values. Treatment-related nonneoplastic lesions were observed in the kidneys consisting of mineralization of the renal papilla, nodular hyperplasia of the pelvic mucosa and pyelonephritis with or without papillary necrosis. No other nonneoplastic treatment-related histopathological change was noted in any other organs.

**Conclusions**

Remarks: Triethanolamine is not carcinogenic and it does not produce histopathological change to the reproductive organs of either male or female rats when administered in the drinking water at dose levels up to approximately 900 mg/kg.

**Data Quality**

Reliability (Klimisch): 2A

Remarks: Reliable with restrictions. Acceptable, well-documented publication/study report that meets basic scientific principles.

**Reference:** Maekawa, A., H. Onodera, H. Tanigawa, K. Furuta, J. Kanno, C. Matsuoka, T. Ogiu, and Y. Hayashi. 1986. Lack of Carcinogenicity of Triethanolamine in F344 Rats. J. Toxicol. Environ. Health 19:345-357.

**Other** Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts.

### D. Reproductive Toxicity

No studies have been conducted to specifically evaluate the effect of triethanolamine on reproductive performance. However, based on consideration of the repeat dose toxicity studies of at least 90 days duration, there were no abnormalities noted in the histopathological examination of reproductive organs. This fact, and the lack of effects on development, allow the conclusion that triethanolamine would not be expected to produce toxicity to reproductive performance and fertility. The OECD SIDS Initial Assessment Report (Report) concurs with this opinion. The Report states, "Although there were no studies available on fertility, there were no abnormalities noted in the histopathological examination of reproductive organs (testes and ovaries) in the 90-day oral and dermal toxicity studies. Triethanolamine is not a developmental or reproductive toxin."

## E. Developmental Toxicity

### Test Substance

| | |
|---|---|
| Identity: | Triethanolamine |
| Purity: | Purest grade commercially available confirmed by gas chromatography (FID). |
| Remarks: | None |

### Method

| | |
|---|---|
| Method/guideline followed: | Chernoff-Kavlock teratogenicity screening test |
| Test type: | Oral |
| GLP: | Yes |
| Species: | Mouse |
| Strain: | CD-1 |
| Number and sex: | 50 mated females in Phase III |
| Route of administration: | Oral gavage |
| Duration of test: | Through day 3 of post partum. |
| Dose level: | 1125 mg/kg |
| Exposure period: | Exposure of females on days 6-15 of gestation. |
| Frequency of treatment: | The test article was administered daily on days 6-15 of gestation. |
| Control group and treatment: | Yes. Identical dosing regimen treatment group with vehicle. |
| Methods: | This study was conducted in 3 phases. Phases I and II were range finding studies designed as a method to identify the appropriate dose for phase III. Phase I was conducted using non-pregnant animals with administration of the triethanolamine daily for 5 consecutive days. Phase II (4 animals/dose) was conducted using pregnant animals with treatment on gestation 6-15. In phase III the animals were evaluated for the following: maternal body weight, maternal mortality and signs of toxicity, implantation sites, pup counts at birth with mortality and pup weight (recorded at birth and on day 3 postpartum). |

### Results

As a result of the mortality rate in the phase II pilot study, the dose chosen for phase III was 1125 mg/kg.

| | |
|---|---|
| NOAEL (NOEL): | 1125 mg/kg |

| | |
|---|---|
| Remarks: | Oral administration of 1125 mg/kg triethanolamine to pregnant mice did not affect maternal mortality, the number of viable litters, length of gestation, litter size, percent survival of the pups or birth weight or weight gained by the pups. |

**Data Quality**

| | |
|---|---|
| Reliability (Klimisch): | 1C |
| Remarks: | Valid with restrictions; Study was conducted according to an established procedure used for screening chemicals for developmental toxicity. |

| | |
|---|---|
| **Reference:** | Pereira, M., P. Barnwell and W. Bailes. 1987. Screening of Priority Chemicals for Reproductive Hazards. Monoethanolamine, Diethanolamine and Triethanolamine. Environmental Health Research and Testing, Inc. Cincinnati, OH. Project # 200-84-2735. |
| **Other** | Arch proposes to develop data to allow the bridge for this endpoint to be made from existing data or information for triethanolamine to polyphosphoric acid esters with triethanolamine, sodium salts. |